REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 46, 51, 54-60 are pending in this application. Claims 46 and 60 have been amended as set forth above to include the limitation "wherein the hydrophilic substance is insoluble at a first range of osmotic pressures and soluble at a second range of osmotic pressures." This limitation makes clearer the preceding limitation "the hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure" and is supported by the specification. See, for example, Example 1.

REJECTION UNDER 35 U.S.C. §102

Claims 46, 51, and 54-60 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartoo et al. Reconsideration of this rejection is respectfully requested.

In order for Bartoo et al. to anticipate claims 46, 51, and 54-60, Bartoo et al. must disclose all the limitations of claims 46, 51, and 54-60. Bartoo et al. disclose an inner wall comprising a hydrophobic substance that is insoluble at a first pH and soluble at a second pH but do not disclose an inner wall comprising a hydrophilic substance that is insoluble at a first range of osmotic pressures and soluble at a second range of osmotic pressures, as recited in amended claims 46 and 60. It would seem that Bartoo et al. would not want a hydrophilic substance having a behavior such as recited in claims 46 and 60 because that might result in the inner wall losing its integrity at the wrong time, for example, while the dosage form is in an acidic solution. The Examiner asserts that in Example 1 of Bartoo et al., the cores of the dosage forms are coated with an inside wall forming composition comprising hydroxypropylmethylcellulose phthalate (HPMCP), cellulose acetate, sorbitol, and polyethylene glycol (PEG). Cellulose acetate and HPMCP are hydrophobic substances. Sorbitol and PEG are hydrophilic substances. Sorbitol and PEG are soluble at any osmotic pressure and do not satisfy the limitation "wherein the hydrophilic substance is insoluble at a first range of osmotic pressures and soluble at a second range of osmotic pressures."

Because Bartoo et al. do not satisfy all the limitations of claims 46 and 60, Bartoo et al. do not anticipate claims 46 and 60. Bartoo et al. also do not anticipate claims 51 and 54-59, because of their dependence from claim 46. Withdrawal of the rejection of claims 46, 51, and 54-60 is respectfully requested.

DECLARATION

The Examiner objected to the Declaration submitted in the previous response as being insufficient to overcome rejection over Bartoo et al. because the data contained therein do not appear to be coming from empirical runs of osmotic dosage forms of the type disclosed in Bartoo et al. The Examiner states that none of the exhibits is an osmotic dosage form, rather individual/single components are used in the determinations/measurements. This is true. It appears that if one desires to know if a hydrophilic substance included in the inner wall of the Bartoo et al. dosage form exhibits a certain behavior one would have to investigate the substances in the inner wall of the Bartoo et al. dosage form individually. The data contained in the Declaration shows that PEG and sorbitol are soluble at any osmotic pressure.

The ability of the aqueous solubility of a hydrophilic substance to respond to osmotic pressure is a property of the hydrophilic substance and can be determined independent of the osmotic dosage form as a whole. The specification of the present application describes a test for screening hydrophilic materials for use in the first membrane a priori (see page 25, line 16^{+}). The examples in the specification of the present application start with evaluation of a number of hydrophilic substances for use in the inner membrane of a dosage form. Samples of hydrophilic materials were immersed in various solutions with osmotic pressures ranging from 0 to 125 atmospheres in order to determine how the materials respond to changes in osmotic pressure. A candidate material which was insoluble in a first range of osmotic pressures and soluble in a second range of osmotic pressures was selected for use in the dosage form.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated October 19, 2006, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC 2762C1).

Respectfully submitted,

Date: December 19, 2006

Adenike Adebiyi

Adenike A. Adebiyi
Reg. No. 42,254
Tel.: (281) 856-8646